JUL - 3 2001

MEDICAL TECHNOLOGIES LTD

Smart Rad™

510 (K) Notification

K003438

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510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92

Submitted by:
Yeshayahu Raz
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Contact person :
Yeshayahu Raz

Date summary was prepared:
10.30.2000

Device trade name:
Smart Rad™

Common Name:
Digital radiography system

Classification name:
Solid State X-Ray Imager (SSXI)

Classification Panel:
Radiology

C. F. R. Section:
892.1650

Product code:
90MQB

CMT Medical Technologies Ltd.,
Smart Rad™ 510 (K) Notification.

Device class:
Class II

Legally marketed devices to which substantial equivalence is claimed:

510 (K) Number	Trade Name	Manufacturer
982795	Philips Bucky-Vision	Philips Medical Systems
983732	Siemens Thorax FD and Multix FD	Siemens Medical Systems
992794	Infimed StingRay DR	Infimed, Inc.
982196	GE Digital Revolution,XQi	General Electric Medical Systems
992547	Canon CXDI-22	Canon USA, Inc.
991578	CMT Smart Spot 2000	CMT Medical Technologies, Ltd.

Device description:
The Smart Rad™ is designed to perform digital radiographic examinations of various anatomic regions in replacement of conventional film-screen. The Smart Rad™ is based on a high resolution (3K x 3K) Solid State X-Ray Imager (SSXI), the Pixium 4600 Flat Panel Detector (FPD) manufactured by Trixel. A typical Smart Rad™ will consist of the FPD mounted in a Bucky, power supplies to the FPD, interfaces to the FPD, to the X-Ray system and to the Bucky, a workstation (computer), monitor and interfaces to a laser imager and communication via Dicom 3.0. The Smart Rad™ will not include the X-Ray system itself.

Intended use of the device:
The **Smart Rad™**, is intended for use in general radiographic examinations, wherever conventional film-screens systems may be used, excluding fluoroscopy, angiography and mammography. **Smart Rad™** allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis and extremities.

Summary of technological characteristics of the device compared to predicates:
The Smart Rad™ has the same technological characteristics as the predicates and performs the same functions, in the same environment. Furthermore, the Smart Rad™ uses the same Solid State X-Ray Imager (SSXI) as the Philips Bucky-Vision, Siemens Thorax FD and Multix FD and Infimed StingRay DR. The Smart Rad™ workstation is based on the CMT Smart Spot 2000 workstation. Detailed comparisons with all predicates are given in Section I.

Clinical and non-clinical study and conclusions:
A clinical evaluation was performed in order to compare radiographic images taken with the Smart Rad™ with standard film-screen images. The results from this study showed that the digital images were comparable or better than film-screen. Non-clinical evaluations of spatial resolution and image contrast supported the diagnostic image quality of the Smart Rad™ images as being equal to or better than film-screen.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2001

Mr. Yeshayahu Raz
Quality Assurance Manager
CMT Medical Technologies, Ltd.
MATAM High Technology Center
HAIFA 31905 ISRAEL

Re: K003438
SMART RAD (Digital Radiographic System)
Dated: April 5, 2001
Received: April 9, 2001
Regulatory Class: II
21 CFR 892.1650/Procode: 90 MQB

Dear Mr. Raz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

CMT

MEDICAL TECHNOLOGIES LTD

Smart Rad™

510(K) Notification

Applicant: CMT Medical technologies, Ltd.

510(k) Number (if known): K003438

Device Name: Trade Name: Smart Rad™
Common name: Digital Radiography System
Classification name: Solid State X-Ray Imager (SSXI)

Indications For Use: The **Smart Rad™,** is intended for use in general radiographic examinations, wherever conventional film-screens systems may be used, excluding fluoroscopy, angiography and mammography. **Smart Rad™** allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis and extremities.

Prescription Use V

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003438

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)